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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,076	12/10/2003	Carlos A. Schuler	53286-US-CNT	7962

1095 7590 03/05/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
PATEL, NIHIR B	

ART UNIT	PAPER NUMBER
3772	

MAIL DATE	DELIVERY MODE
03/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,076	SCHULER ET AL.	
	Examiner	Art Unit	
	NIHIR PATEL	3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. In view of the Appeal Brief filed on November 5th, 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Patricia Bianco/.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims **1-21** are rejected under 35 U.S.C. 102(b) as being anticipated by Kropp (US 3,636,949).

4. **As to claim 1,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position **(see figs. 2 and 3; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, the contact member being movable between a first position and a second position, wherein a portion of the metering valve is able to contact the contact member when the first position **(see fig. 3; col. 4 lines 25-35)** and is unable to contact the contact member when in the second position **(see fig. 2; see col. 4 lines 60-70)**.

5. **As to claim 2,** Kropp teaches an apparatus wherein the metering vale may be moved to the actuated position only when the contact member is in the first position **(see figs. 2 and 3)**.

6. **As to claim 3,** Kropp teaches an apparatus wherein the container and the metering valve are movable within the housing and wherein when the contact member is in the first position, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second position, the metering valve is unable to contact the contact member and cannot be moved into the container to the actuated position **(see figs. 2 and 3; col. 4 lines 25-35 and lines 60-70)**.

7. **As to claim 4,** Kropp teaches an apparatus that comprises a controller adapted to selectively control the movement of the contact member **66 and 67 (the ball and cord define the controller that controls the movement of the contact member)**.

8. **As to claims 5 and 10,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position **(see figs. 2 and 3; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, the contact member having a first configuration and a second configuration, wherein a portion of the metering valve is able to contact the contact member when in the first configuration in a manner which allows the metering valve to be moved to the actuated position **(see figs. 2 and 3)**, and wherein a portion of the metering is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuated position **(see figs. 2 and 3; because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord it is inherent that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position)**.

9. **As to claim 6,** Kropp teaches an apparatus wherein the metering valve may be moved to the actuating position only when the contact member is in the first position **(see figs. 2 and 3)**.

10. **As to claims 7 and 16,** Kropp teaches an apparatus wherein the container and the metering valve are movable within the housing and wherein when the contact member is in the first configuration, the metering valve is able to contact the contact member so that it may be moved into the container to the actuated position and when the contact member is in the second configuration, the metering valve is able to contact the contact member but cannot be moved into the container to the actuated position **(see figs. 2 and 3; because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord it is inherent that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position)**.

11. **As to claim 8,** Kropp teaches an apparatus wherein the contact member is rigid in the first configuration and is flexible in the second configuration **(see figs. 2 and 3).**

12. **As to claims 9, 17, 19 and 21,** Kropp teaches an apparatus that comprises a controller adapted to selectively control the movement of the contact member **66 and 67 (the ball and cord define the controller that controls the movement of the contact member)**.

13. **As to claim 11,** Kropp teaches an apparatus wherein the first condition is a first position and wherein the second condition is a second position **(see figs. 2 and 3)**.

14. **As to claim 12,** Kropp teaches an apparatus wherein the first position is a position in the housing where the contact member may contact a portion of the metering valve **(see figs. 2and 3)**.

15. **As to claim 13,** Kropp teaches an apparatus wherein the first condition is a first configuration and wherein the second condition is a second configuration, and wherein the first configuration is a rigid configuration **(see fig. 3).**

16. **As to claim 14,** Kropp teaches an apparatus wherein the second configuration is a relatively flexible configuration **(see fig. 2)**.

17. **As to claim 15,** Kropp teaches an apparatus wherein the metering valve may be moved to the actuating position when the contact member is in the first condition **(see fig. 2)**.

18. **As to claim 18,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position **(see figs. 2 and 3; col. 4 lines 60-67 and col. 5 lines 1-5)**, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member **(see fig. 3)** and may not be actuated when the metering valve and/or container is unable to contact the contact member **(see fig. 2)**.

19. **As to claim 20,** Kropp teaches an apparatus that comprises a housing **11 (see fig. 1 col. 3 lines 40-50)**; a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant; a metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** in communication with the reservoir, the metering valve being movable into the container to an actuated position **(see figs. 2 and 3; col. 4 lines 60-67 and col. 5 lines 1-5)**,

wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position; and a contact member **68** in the housing, wherein the metering valve may be moved to the actuated position when the metering valve and/or the container is able to contact the contact member **(see fig. 3)** in a rigid configuration and may not be actuated when the metering valve and/or container is unable to contact the contact member is a rigid configuration **(see figs. 2and 3)**.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. Claims **22-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropp (US 3,636,949).

23. **As to claims 22-25,** Kropp substantially discloses method steps of controlling the operation of an aerosolization device that comprises a container **20 (see fig. 2; col. 3 lines 50-60)**

comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** being movable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method step comprising positioning a contact member in a first position where the contact member may contact the metering valve and/or the container to allow the metering valve to be moved to the actuation position **(see fig. 3)** and positioning the contact member in a second position where the metering valve may not be moved to the actuation position **(see fig. 2)**.

The method steps would have been obvious because they would have resulted from the use of the device of Kropp.

24. **As to claims 26-30,** Kropp substantially discloses method steps of controlling the operation of an aerosolization device that comprises a container **20 (see fig. 2; col. 3 lines 50-60)** comprising a reservoir storing a pharmaceutical formulation which comprises a propellant, and the aerosolization device comprising a metering valve in communication with the reservoir, the metering valve **21.1 (see fig. 2; col. 3 lines 50-60)** being movable into the container to an actuated position, wherein a predetermined amount of the pharmaceutical formulation is released when the metering valve is moved to the actuated position, the method step comprising configuring a contact member in a first configuration wherein the contact member may contact the metering valve to allow the metering valve to be moved to the actuated position **(see fig. 3)**; and configuring the contact member in a second configuration wherein the metering valve may n contact the contact member but may not be moved to the actuated position **(see figs. 2 and 3;**

because the contact member is controlled by the cord and ball and depends on the amount of pressure being applied to the ball or cord, therefore it is obvious that the a portion of the metering valve is able to contact the contact member when in the second configuration in a manner which does not allow the metering valve to be moved to the actuation position).

The method steps would have been obvious because they would have resulted from the use of the device of Kropp.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772